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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,305	10/15/1999	KAZUHIKO MARUTA	MARUTA=3C	1033
1444	7590	11/25/2003	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			PROUTY, REBECCA E	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/419,305

Applicant(s)

MARUTA ET AL.

Examiner

Rebecca E. Prouty

Art Unit

1652

--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 1.Claim(s) withdrawn from consideration: none.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Rebecca E. Prouty  
Primary Examiner  
Art Unit: 1652

Continuation of 5. does NOT place the application in condition for allowance because: the amendment to Claim 1 do not overcome the enablement and new matter rejections of the claim. While as applicants argue the specification provides support for variants of SEQ ID NO:1 in which one or more amino acids are replaced, deleted or added, the further limitation of not having the amino acid sequence of SEQ ID NO:3 and/or SEQ ID NO:4 defines a subgenus not contemplated in the specification as filed. As such this recitation introduces new matter. Applicants argue that the enablement rejection should be withdrawn as mutagenesis techniques as well as assay techniques are routine in the art and could be used to define substitutions which could be made. While such techniques might be sufficient for one of ordinary skill in the art to make and use variants with only a few substitutions by making several variants and testing for those which retain the claimed properties, such experimentation would clearly be undue for those polypeptides with large numbers of substitutions as the likelihood of a variant sequence retaining the claimed properties of the native polypeptide decreases substantially with each additional mutation while the number of possible variants which could be made increases exponentially. As such the claimed variants (i.e., those which retain the claimed physicochemical properties of the native polypeptide) with larger numbers of mutations are a very minute fraction of the possible variants which could be made and the experimentation required to make and test all the possibilities would clearly be undue. .